REMARKS

Applicants have amended the specification and claims to more particularly define the invention taking into consideration the outstanding Official Action. The Abstract of the Disclosure has been amended to remove the objected to phraseology as required by the Examiner. Accordingly, it is most respectfully requested that the objection to the Abstract be withdrawn. The Examiner is authorized to make whatever further amendments to the Abstract the Examiner may require.

Claims 1, 3, 8, 13, 15, 19, 25, 26 and 27 have been amended and new claims 32-39 have been added to the application. Claim 1 is now limited to a method of producing a synthetic bone material for use in biomedical applications as is fully supported by Applicants' specification including the original claims, see claims 21-23, for example. In addition, the preferred aspects of the claims have been made the subject of separate dependent claims. The claims now remaining in the application are claims 1-27 and 32-39. Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claims 1-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been carefully considered. Claims 1, 3, 8, 13, 15, 19, 25, 26 and 27 have been amended to correct the various rejections under 35 U.S.C. 112, second paragraph, and therefore, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1 and 4-27 under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

At the outset, Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic

criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants most respectfully submit that a prima facie case of obviousness of the presently claimed subject matter has not be established as it is submitted that it would not have been obvious to modify the process described in WO 93/04013 in view of the disclosure of US 5,895,897.

Amended claim 1 is directed to "A method of producing a synthetic bone material for use in biomedical applications, said synthetic bone material comprising a macroporous ceramic foam which has an open foam structure containing pores and having an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm...". Thus, the claimed method is concerned with making a synthetic bone material for biomedical applications (see page 1, lines 1 to 5 of Applicants' specification).

The term "macroporous" means an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm (see the text on page 4, lines 14 to 17). These are claim limitations which cannot be ignored.

Claim 1 is further limited in that the step of foaming the ceramic slip in step (b) is carried out using a ball mill.

Claim 1 is novel over WO 93/04013 for at least the reason that this prior art document does not disclose the step of foaming a ceramic slip using a ball mill (step (b)). It is clear that WO 93/04013 achieves foaming by the injection of gas into the dispersion. Claim 1 is further distinguished from WO 93/04013 in that the claimed method is directed to a method of producing a macroporous ceramic foam for use in biomedical applications and having an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm.

Accordingly, claim 1 differs from WO 93/04013 by virtue of at least the feature of foaming the ceramic slip using a ball mill and also in that the ceramic foam is a macroporous ceramic foam for use in biomedical applications having an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm.

In an effort to overcome the deficiencies of the primary reference, the Official Action relies on the teachings of US 5,895,897. This document is directed to a light-weight ceramic acoustic absorber for use in the exhaust nozzles of a jet engine. It is, accordingly, clear that US 5,895,897 lies in a completely different technical field from that of the present invention, i.e. synthetic bone materials for biomedical applications. Applicants most respectfully submit that the skilled person, seeking to improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of WO 93/04013 based on the teaching of US 5,895,897. In particular, there is no suggestion in either WO 93/04013 or US 5,895,897 that the use of a ball mill to achieve foaming of a ceramic slip would result in an improved biomedical ceramic material. Accordingly, there would be no motivation for the skilled person to combine the teachings of WO 93/04013 and US 5,895,897. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.).

It is further noted that the method according to WO 93/04013 does not appear to result in a porous foamed ceramic structure that would be suitable for use as a biomedical material (e.g. a bone graft substitute) as contemplated by the present application. For this purpose, the foamed macroporous ceramic material must exhibit

open porosity, as opposed to closed porosity, and must have a modal pore size ≥100 μm. This is clearly discussed in the description of the present application (see pages 4 and 5) and reflected by the wording of claim 1. Indeed, the reference to the Buchner funnel in Examples 2, 3 and 4 of WO 93/04013 would be expected to result in pores having a similar size to that of the filter, i.e. 10 to 16 μm.

As already stated, document US 5,895,897 does not disclose a method of producing a synthetic bone material for use in biomedical applications, e.g. for use as a bone graft substitute. There is also no indication that the ceramic according to US 5,895,897 has an open macroporous structure with a modal pore size ≥ 100 μm, as required by claim 1 of the present application.

Thus, there would be no motivation for one skilled in the art to combine documents WO 93/04013 and US 5,895,897. There is no indication in either documents that ball milling could or should be used to achieve the required macroporous open foam structure, which is necessary for certain biomedical applications. Indeed this feature is clearly precluded by document WO 93/04013. Even in the unlikely event that the documents were combined, neither document teaches or suggests that foamed macroporous ceramic material has open porosity (as opposed to closed porosity) with a modal pore size ≥ 100 μm. Thus, the combination of references cannot render the claims prima facie obvious.

As discussed in the present application on pages 8, 9 and 21, there are a number of advantages associated with ball milling foam-stabilised slips, including:

(i) No organic sponge/foam template or solid pore-formers to burnout; porous ceramics produced by burnout methods often have relatively low mechanical properties resulting from defects in the structure due to incomplete/irregular burnout of the original template;

(ii) Homogeneous or functionally graduated pore distributions are attainable by varying the slip viscosity;

(iii) Macro-pore size is variable by varying the start-powder particle size; (iv) Macro-porosity is highly interconnected; and

(iv) Microstructure contains an interconnected network of micro-pores, the degree of connectivity of which can be controlled during sintering. This is important for tailoring the drug delivery characteristics of the porous structure.

These advantages enable control of the pore structure so as to minimize batch variation and the production of substantially isotropic open structures. The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements. It is pointed out that all the Examples featured in the present application rely on the use of a ball mill to achieve foaming of the ceramic slip. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over WO 93/04013 in view of Oishi et al, as applied to claims 1 and 4-27 above, and further in view of WU has been carefully considered but is most respectfully traversed.

The Examiner alleges that (former) claims 2 and 3 are obvious having regard to WO 93/04013 in view of US 5,895,897 and US 5,656,562.

US 5,656,562 relates to a method of improving the properties of ceramic green bodies. While US 5,656,562 does mention the use of a ball mill, this is not used to prepare a foamed ceramic. Instead, the ball mill is merely used to prepare (i.e. mill) the starting powders. This is clear from column 5, lines 31 to 42, were, the powders are milled and then separated from the grinding media. Only then is a slurry formed by adding deionized water. Thus, US 5,656,562 merely describes the conventional technique of using grinding media to mill starting powders. US 5,656,562 is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications. In view of the above comments, it is considered that the disclosure of US 5,656,562 has been taken out of context and the Examiner's rejection should most respectfully be withdrawn.

Applicants note that the present application is the national stage of a PCT application and in the Notice of Acceptance, there is an indication that the priority document is on file. Accordingly, it is most respectfully requested that in the next Official

Action, the claim for foreign priority be acknowledged as well as receipt of the priority document.

In addition, the application contains formal drawings and it would be appreciated if the next Official Action acknowledges acceptance of the drawings.

In view of the above comments and further amendments to the specification and claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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Marked-Up V rsi n Showing Changes Made

IN THE SPECIFICATION:

Please replace the original Abstract of the Disclosure with the following amended Abstract of the Disclosure on a separate sheet of paper. The marked-up version showing the changes made are on the marked-up copy after the amendment.

[The present invention relates to a] A method for the production of a macroporous ceramic foam, [which method comprises] wherein: (a) forming a ceramic slip comprising a substantially homogeneous mixture of a ceramic particulate, an organic binder in a liquid carrier, and optionally one or more surfactants, wherein at least one surfactant is present if the organic binder does not function as a surfactant, and wherein the ceramic slip preferably has a viscosity in the range of from 15 to 200 $mPas^{-1}$; (b) foaming the ceramic slip; and (c) heating the foamed ceramic slip at a temperature sufficient to substantially burn out the organic binder. The macroporous ceramic foam is suitable for use in biomedical applications such as synthetic bones, tissue engineering scaffolds or drug delivery devices.

IN THE CLAIMS:

Please replace claim 1 with the following amended claim 1.

1(Amended). A method of producing a [macroporous ceramic foam] synthetic bone material for use in biomedical applications , said synthetic bone material comprising a macroporous ceramic foam which has [and having] an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm, which method comprises:

(a) forming a ceramic slip comprising a substantially homogeneous mixture of a ceramic particulate,

an organic binder in a liquid carrier, and

optionally one or more surfactant, wherein at least one surfactant is present if the organic binder does not function as a surfactant [, and wherein the ceramic slip preferably has a viscosity in the range of from 15 to 200 mPas];

(b) foaming the ceramic slip using a ball mill; and

(c) heating the foamed ceramic slip at a temperature sufficient to substantially burn out the organic binder.

Please replace claims 3, 8, 13, 15, 19, 25, 26 and 27 with the following amended claims.

3(Amended). A method as claimed in claim 2, wherein the balls of the milling media have a diameter in the range of from 10 to 30 mm[, preferably from 15 to 25 mm].

8(Twice Amended). A method as claimed in claim 1, wherein the ceramic particulate has a d_{50} of from 1 to 300 μm[, preferably from 1 to 15 μm].

13(Amended). A method as claimed in claim 12, wherein the organic binder is present in the liquid carrier in an amount of from 0.5 to 6 w/v%[, preferably from 0.5 to 4 w/v%].

15(Amended). A method as claimed in claim 14, wherein the ceramic slip comprises from 20 to 90 w/v% ceramic particulate[, preferably from 40 to 80 w/v% ceramic particulate].

19(Twice Amended). A method as claimed in claim 17, wherein the concentration of the organic binder in the liquid carrier is selected such that the percentage of binder remaining after substantially all of the liquid carrier has [bene] <u>been</u> evaporated is from 0.5 to 10 w/w%.

25. (Twice Amended) A method as claimed in claim 23, wherein the sintered ceramic foam has a bulk porosity in the range of from 40 to 95%[, preferably from 70 to 90%].

26. (Twice Amended) A method as claimed in claim 1, wherein the sintered ceramic foam has a strut density in the range of from 60 to 95%[, preferably from 70 to 90%] of the theoretical density of the ceramic.

27. (Twice Amended) A method as claimed in claim 23, wherein the sintered ceramic foam has a modal pore size in the range of from 100 to 2000 μm[, preferably from 100 to 1000 μm].